ELAB Performance Based Measurement System Subcommittee Report July 1997

The Subcommittee had numerous conference calls to finalize the wording of the two remaining recommendations and identifying other issues. The four recommendations (including two that were approved in January 1997) are:

- ELAB should encourage senior EPA officials to advocate the highest level of coordination and consistency between the various Program Offices in their implementation of PBMS. [Approved]
- 1. PBMS training programs for state and/or federal assessors or inspectors should be established prior to implementation of PBMS. [Approved]
- 2. ELAB recommends that before EPA promulgates a regulation, it must demonstrate & document that MQOs are achievable using available measurement technology.
- 3. EPA must demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.)

Other issues identified include those dealing with definitions.

PB Measurement System vs. PB Method

There is some confusion with what is a PBMS and what is a PBM. One way to differentiate them is to consider PBMS as allowing any method to be used to satisfy the objectives of the analysis. Each variation to a method would be described or labeled. For PBM, modifications to existing methods would be allowed and the use of that method name and number could still be used. This would be important in the case of permits where methods are specified. Under PBM, variations of a method retain the method name and number and are equivalent to the original method.

Sample matrix

Validation of methods are usually described via a particular matrix. What are equivalent matrices for QC purposes? What characteristics should be considered? This will be a serious issue if regulators and assessors don't agree.

Method Validation

Definition is needed so that both labs and assessors know what criteria are needed to validate a method. This is critical since only a validated method can be considered equivalent to existing methods.

Other issues which are still on the table:

Assessor Training

PBMS is a new paradigm with different issues. There will be fewer pre-defined method characteristics and performance criteria for assessors to review. They will need more time to read new methods and assess their validation. Uniformity of assessments will be more difficult.

Method Compliance

Will PBMS methods be approved or equivalent to existing or reference methods and be as legally defensible? Provisions are needed which will guarantee that any method that meets a given Program Office's PBMS criteria will have completely equal legal authority. If this issue is not adequately addressed to assure the permittee full acceptance of their data, then the regulated community is not likely to undertake the risk of having their data judged unacceptable.

Interlaboratory Comparability

Concern that using different variations of a method will give different results by different labs. How is industry to be assured that data is comparable? Which would be the "correct" result?

Cost

Expectations are for cost savings, but an increase in QA/QC samples may increase cost. Also, increased validation needs, due to more matrices or higher levels of validation, may increase cost as well.

Laboratory Client Relationship

Changing role of the lab from merely analyzing samples to being involved with sampling, choosing appropriate methods, and defining data packages. Does the lab move away from doing unbiased objective testing?

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